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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATEL, MITAL B	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,449	GIESCHEN ET AL.	
	Examiner	Art Unit	
	Mital B. Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19-22* is/are allowed.

6)☒ Claim(s) *1-18,23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 2/22/05 have been fully considered but they are not persuasive.

2. In response to Applicant's arguments that Hurka et al does not teach an open central interior, element 3 is an open central interior in which the bead moves about and thus does not teach away from an open central interior as contended by Applicant.

3. In response to Applicant's arguments with respect to claim 6, the Examiner maintains that the non-smooth surface would allow for some chaotic movement of the bead as the bead "bounces" off the non-smooth surface. Furthermore, Applicant has not limited the claim to recite a non-orbital path.

4. In response to Applicant's arguments regarding claim 7, the claim does not require that there is movement of the dose from a platform or area outside of the dispersion chamber into the dispersion chamber. The claim merely recites that the dose platform **holds** a dose of dry powder pharmaceutical. A feature of the movement of the powder as argued is not recited in the claim.

5. In response to Applicant's arguments with respect to claim 8, the Examiner maintains that the non-smooth surface would allow for some chaotic movement of the bead as the bead "bounces" off the non-smooth surface. Furthermore, Applicant argues that there is no disclosure in Hurka et al. of changing the direction of ball movement. However, such a feature is not positively recited in the claim.

6. In response to Applicant's above arguments that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. In response to Applicant's comments regarding claim 10, the Examiner would like to clarify that Hurka et al teaches the dispersion chamber to be a separate, removable component from the cover sheet 2 and outlet 8.

8. In response to Applicant's arguments regarding claim 16, the Examiner has considered the arguments but did not find them to be persuasive as Examiner still maintains the rejection set forth previously.

9. In response to Applicant's arguments with respect to claim 18, the Examiner maintains the previous rejection set forth as the claim does not require movement of the substance into the dispersion chamber during inhalation but merely requires the blister container to be supported on the inlet and to contain a dose of the powder. Furthermore, the claim does not recite the features of reusable, environment-sealed, or compact-packaged, nor does the claim recite any airflow characteristics.

10. In response to Applicant's arguments with respect to the dimensions of the bead being at least 50-90%, it should be noted that the bead(s) taught by Hurka et al. **are at least** 50-90%. The claim does not require the bead to be at or between 50-90%. Furthermore, the claim does not recite the features of contact, collisions, and/or shear effects.

11. In view of the above comments, the Examiner maintains the previous rejections set forth.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 15, 17, 23, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurka et al (US 4,841,964).

14. **As to claim 1**, Hurka et al teaches an inhaler (**See Figs. 1-14**) for providing a dose of a dry powder pharmaceutical to a patient, comprising: a dispersion chamber **1,3** having an open central interior; at least one bead **4** in the dispersion chamber, with the bead having a characteristic dimension of at least 50 to 90% of an interior height of the dispersion chamber (**See Col. 8, lines 55-67**); an inlet **6** connecting into the dispersion chamber; and an outlet **8** connecting into the dispersion chamber and spaced apart from the inlet.

15. **As to claim 2**, Hurka et al teaches an inhaler wherein the dispersion chamber includes an inner wall forming a bead race (**that formed by 3**), and wherein the bead moves around the bead race upon inhalation by the patient (**See Col. 5, lines 32-46, Col. 6, lines 39-58**)

16. **As to claim 3**, Hurka et al teaches an inhaler wherein the bead race has a radius of curvature greater than a radius of curvature of the bead (**See Col. 5, lines 32-46 and Col. 8, lines 55-67, wherein the smaller bead would have a radius of curvature less than that of the bead race**) .

17. **As to claim 4**, Hurka et al teaches an inhaler wherein the dispersion chamber has a flat bottom surface and a flat top surface adjoining the bead race (**See Figs. 1, 5, 8, and 9**).

18. **As to claim 5**, Hurka et al teaches an inhaler further comprising means **2** for retaining the bead in the chamber.

19. **As to claim 6**, Hurka et al teaches an inhaler wherein the bead moves around chaotically in the dispersion chamber when a patient inhales on the outlet (**See Col. 7, lines 37-61 which disclose non-smooth surfaces of the orbit path which would result in chaotic movement of the bead in the bead race**).

20. **As to claim 7,** Hurka et al teaches an inhaler further comprising a dose platform adjacent to the inlet, for holding a dose of dry powder pharmaceutical (**See Col. 8, lines 35-38 wherein the surface of the orbital path serves as the dose platform**).

21. **As to claim 8**, Hurka et al teaches an inhaler further comprising an obstruction (**See Col. 7, lines 50-56, wherein the grooves are considered to be an obstruction**) in the dispersion chamber to cause the bead to move chaotically.

22. **As to claim 10**, Hurka et al teaches an inhaler wherein the dispersion chamber comprises a separate component, installable into, and removable from the inhaler (**See Fig. 5**).

23. **As to claim 11**, Hurka et al teaches an inhaler wherein a plurality of beads (**See Col. 8, lines 55-64; See also Col. 3, lines 12-20**) are located in the dispersion chamber, and wherein at least one of the beads includes a discontinuity (**See Col. 7, line 45-47 wherein a golf ball structure is disclosed which structure would have discontinuity**).

24. **As to claim 12**, Hurka et al teaches an inhaler wherein the bead having the discontinuity is polygonal shaped, and the discontinuity comprises a corner (**See Col. 7, line 45-47 wherein a golf ball structure is disclosed which structure would be a spherical polygon having a corner**).

25. **As to claim 13**, Hurka et al teaches an inhaler wherein the bead having the discontinuity comprises a sphere with a flat surface (**See Col. 7, line 45-47 wherein a golf ball structure is disclosed which structure would be a spherical polygon also have portions which are flat surfaced**).

26. **As to claim 15**, Hurka et al teaches an inhaler wherein from 2 to 10 rounds beads are provided in the dispersion chamber (**See Col. 8, lines 55-64**).

27. **As to claim 17**, Hurka et al teaches an inhaler wherein the dispersion chamber has a characteristic dimension that is from 4 to 20 times greater than the characteristic dimension of the bead (**See Col. 8, lines 55-64; See also Col. 3, lines 12-20**).

28. **As to claim 23**, Hurka et al teaches an inhaler with the open central interior in the same place as the bead race (**See Fig.2**).

29. **As to claim 24**, Hurka et al teaches an inhaler (See Figs. 1-14) comprising a dispersion chamber **1,3** having an open central interior; at least one bead **4** in the

dispersion chamber; an inlet **6** connecting into the dispersion chamber; an outlet **8** connecting into the dispersion chamber and spaced apart from the inlet; and the dispersion chamber includes an inner wall (**the dispersion chamber inherently includes an inner wall as the inhaler is an enclosed element)** forming a bead race, and wherein the bead moves primarily, but not exclusively, around the bead race upon inhalation by the patient.

30. **As to claim 25**, Hurka teaches an inhaler wherein the open central interior allows one or more beads in the dispersion chamber to substantially move around in the dispersion chamber in an at least partially non-uniform manner (**it should be noted that any movement of the inhaler by the patient as the patient is using the inhaler would result in the bead moving in a non-uniform manner**).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

33. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

34. Claims 9, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurka et al (US 4,481,964).

35. **As to claim 9**, Hurka et al teaches essentially all of the limitations except for the specifics regarding the electrical charge of the bead and the particles of the dry powder. However, such a charge would depend on the type of bead and type of pharmaceutical agent used. It should be noted that in the embodiment taught by Hurka that does not involve coating of the pharmaceutical to the bead, the particles inherently would have to have the same charge of polarity as the bead, otherwise all the particles would be stuck on the bead and not be available to the user for inhalation.

36. **As to claim 16**, Hurka et al teaches essentially all of the limitations except for wherein the beads move around the dispersion chamber at 4000-10,000 rpm. It should be noted that in Col. 5, lines 38-45, a range of 300 to 3000 rpm is disclosed by Hurka et al. Additionally, Hurka et al teach that depending on the chosen pressure difference

and ball tolerance, the rotational speed will vary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to arrive at the above limitation depending on the pressure difference and ball tolerance.

37. **As to claim 18**, Hurka et al teaches an inhaler (**Figs. 1-14**) for providing a dose of a dry powder pharmaceutical to a patient, comprising: a dispersion chamber **1,3** having an open central interior; at least one bead **4** in the dispersion chamber, with the dispersion chamber having an interior characteristic dimension that is 4 to 20 times greater than a characteristic dimension of the largest bead in the dispersion chamber (**See Col. 8, lines 55-64; See also Col. 3, lines 12-20**); an inlet **6** connecting into the dispersion chamber; and an outlet **8** connecting into the dispersion chamber and spaced apart from the inlet. Hurka et al fails to disclose a single unit dose blister container supported on the inlet, and containing a single dose of dry powder pharmaceutical, however, the use of such blister containers is well known in the powder inhaler art and it would have been obvious to one of ordinary skill in the art at the time of the invention to provide such a blister container since Hurka et al discloses the use of any dry powder pharmaceutical to be used with a single inhaler.

Allowable Subject Matter

38. Claims 19-22 are allowed over the prior art of record.

39. The following is a statement of reasons for the indication of allowable subject matter: As to claim 19, the prior art of record does not teach nor render obvious the overall claimed combination if an inhaler having a chamber ring extending partially into

the bead chamber, for preventing any bead from moving out of the dispersion chamber and into the outlet.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/13/05

Mital B. Patel
Examiner
Art Unit 3743

mbp